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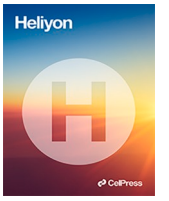

Research article

Effectiveness of couple-based health education on utilization of maternity waiting homes among pregnant women in rural Ethiopia: A study protocol for cluster-randomized trial

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ABSTRACT

Background: Maternity waiting homes are used to enhance women's access to health facilities in low-resource settings; however, its use remains low in Ethiopia. It is important to investigate strategies that can enhance the usage of maternity waiting homes in Ethiopia.
Methods: The purpose of his study is to assess how well couple-focused health education works to increase maternal knowledge, attitudes, and use of maternity waiting homes in rural Ethiopia. A cluster-randomized trial with two parallel groups will be the study's design. Three hundred twenty samples will be drawn from 16 clusters (160 in each group). Clusters will be assigned to intervention or control groups using a restricted randomization with a 1:1 allocation ratio. Women who are in their 14–16 weeks of gestation, or in the early stages of their second trimester, along with their male partners, will participate in the study. Health education, home visits, and the distribution of leaflets will be the intervention packages.
Discussion: The trial results will provide conclusive evidence on whether couple-based health education can improve women's access to maternity waiting homes in rural Ethiopia.

1. Introduction

Maternity waiting homes (MWH) are acknowledged as a way to enhance the health outcomes of women who have restricted access to obstetric facilities due to geographical and transportation constraints [1,2]. They are places for women to stay in the final 2–3 weeks of gestation and are often found next to or inside health facilities [3]. The World Health Organization (WHO) advises use of MWHs to enhance women's health outcomes, especially in underdeveloped nations such as Ethiopia [4]. Accordingly, Ethiopia has been implementing MWHs for several decades [5].

However, MWH use was found to be low in Ethiopia [6], and women's access to it mainly depended on male partner (husbands') decisions [7,8]. Male partners have important responsibilities, such as making decisions and setting up funds for the mother and infant to utilize during MWH stays, as well as for food, cleaning supplies, and transportation [9]. Men's participation in women's health

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improves care-seeking behavior, homecare practices, candid communication between partners, and cooperative decision making [10, 11]. This suggests that integrating male partners in women's health could enhance the use of MWHs and other maternal health services. Lack of knowledge of MWHs, opinions of the services as being of low quality, poor providers interactions with MWH users, staffing deficit, and home tasks were among the obstacles to MWHs [8,12,13].

Moreover, the WHO advised research regarding what methods could be effective in enhancing access to MWHs and other maternal health services [4]. This trial will examine the effect of health education delivered to couples on MWH use in rural Ethiopia using a cluster randomized trial (CRT) design. The CRT design is selected for pragmatic reasons and to reduce the possibility of information exchange regarding the intervention among control and experimental groups. The information exchange may happen due to the participants' involvement in various social occasions including marketing and religious gatherings, and marriage and burial ceremonies.

2. Methods and materials

2.1. Objective

This CRT will measure the effectiveness of health education delivered to pregnant women and their spouses in improving their knowledge of and attitude towards MWHs as well as usage of MWHs in Hadiya Zone, Ethiopia.

2.2. Study design

The study design will be a cluster randomized trial with two parallel groups.

2.3. Study setting

This research will be conducted in the Hadiya Zone of Southern Ethiopia. Hadiya Zone is a second-order administrative division located in Southern Ethiopia. It is divided into four town administrations and 13 rural districts, with a total of 359 clusters (Kebele's). Kebele (here in after called cluster) is the smallest administrative unit. The livelihoods of the population depend mainly on agriculture. There were four public hospitals, 61 health centers, 317 health posts, and 30 MWHs. The total population was approximately 1.2 million of which 619,170 were women [14]. According to an annual report from the Hadiya Zone Health Department in 2022, approximately 60,304 women were estimated to be pregnant.

2.4. Sample size calculations

The Hooper and Bourke techniques for CRT of parallel arms with repeated measures were used to compute the sample size [15]. To demonstrate the within and between intracluster correlation coefficients (ICC), the procedure encompasses the measurement of two design effects, with the product of the two being applied to inflate the sample size for individual-level randomization. The within ICC is the relationship between any two participants in the same cluster, while the between ICC is the relationship between any two participants in different clusters. The first design effect (d_c) owing to cluster-randomization was determined using a within ICC of 0.05 gained from a CRT in Ethiopia [16]. The design effect owing to randomization of clusters (d_c) was computed as:

$$d_c = 1 + (m-1)\rho$$

Where: m is the cluster-size supposed to be 20 (i.e., the number of participants who will be questioned in a cluster) and ρ is the within ICC.

The second design effect (d_r) owing to repeated assessments (baseline/endline) was computed by using the within ICC and a cluster autocorrelation coefficient (π) of 0.80 [15].

The second design effect owing to repeated assessments (d_r) was calculated as:

$$d_r = \left(1 - r^2\right)$$

Where: $r = \left(\frac{m\rho\pi}{d_c}\right)$.

The required sample size was then determined by multiplying the '*sample size assuming individual randomization*' by the two design effects (d_c & d_r). It was computed as:

$$n = \left\lfloor \frac{(a+b)^2 * (p_1q_1 + p_2q_2)}{\left(|p_1 - p_2|\right)^2} \right\rfloor * d_c d_r$$

Where:

n denotes the sample size in each group i.e., intervention and control arms;

a denotes the conventional multiplier (1.96) for alpha $(\alpha = 0.05)$ and b symbolizes the conventional multiplier (0.842) for power $(1 - \beta = 0.80)$;

p_1 denotes percentage of users of MWHs after intervention and q_1 represents percentage of non-users of MWHs after intervention;

p_2 denotes percentage (=50 %) of users of MWHs from a study in Gurage Zone, Ethiopia [17] and q_2 symbolizes before-intervention percentage of non-users of MWHs; and

$|p_1 - p_2|$ *an effect size* - is an absolute change in percentage of MWH usage after intervention. The *effect size* was estimated to be 20 %.

Furthermore, the following factors were considered in the sample size determination: 95 % CI 80 % power, 1:1 allocation ratio of intervention to control, 10 % loss to follow-up, and tabulated sample size ($n_0 = 199$) required to detect a difference in two proportions at 0.05 significance level with 80 % power in the literature [18]. Per Hooper and Bourke methods, the number of clusters (K) for the sample is calculated using the formula $K = (n_0 d_c d_r)/m$. In the current protocol, the final sample size was determined by replacing the specified values into the above mentioned formula. Hence, a total of 16 clusters are required, with an estimated sample size of 320. The two arms each will have 160 participants (160 pairs of women with their male partners).

2.5. Sampling procedures

The selection of clusters will be performed based on the availability of MWHs. We will select the required 16 clusters from the catchment of health facilities with MWHs. These clusters will be randomly allotted to intervention or control arms. Census and health post-records will be used to detect eligible participants, resulting in the creation of a sampling frame. Then a simple random sampling technique will be used to select the participants. Each cluster will contribute 20 participants (20 couples). The same sample of participants evaluated before intervention will be evaluated at the end of the intervention to determine the outcome (Fig. 1).

2.6. Eligibility criteria

Pregnant women with their male partners (spouses) will be the participants. They should be at the beginning of 2nd trimester (14–16 weeks of gestation), permanent inhabitants of the study area, who had a history of delivery in the last 5 years, living with their spouses, living ≥2 h of walking distance from a medical facility, have limited access to public transport, and whose spouses are ready to involve in the study.

2.7. Participants' selection

Hadiya Zone was one of lowest performers in Southern Ethiopia regarding MWH use in 2022 according to the annual regional report. This situation drew the attention of the researchers to perform this study in this area. First, health centers with functional MWHs will be identified (S1 Appendix). One health center serves an estimated 25,000 population with a catchment of five clusters. Each cluster contributes 5000 population. Secondly, all the clusters under each health center catchments will be listed. Thirdly, all non-adjacent clusters located relatively far from the nearest health centers will be identified. Next, 16 non-adjacent clusters will be chosen.

Then, the selected 16 non-adjacent clusters will be randomly assigned to intervention and control groups. Census and/or health post records will be used to identify pregnant women. Then, women will be asked their Last Menstrual Period (LMP) to estimate the

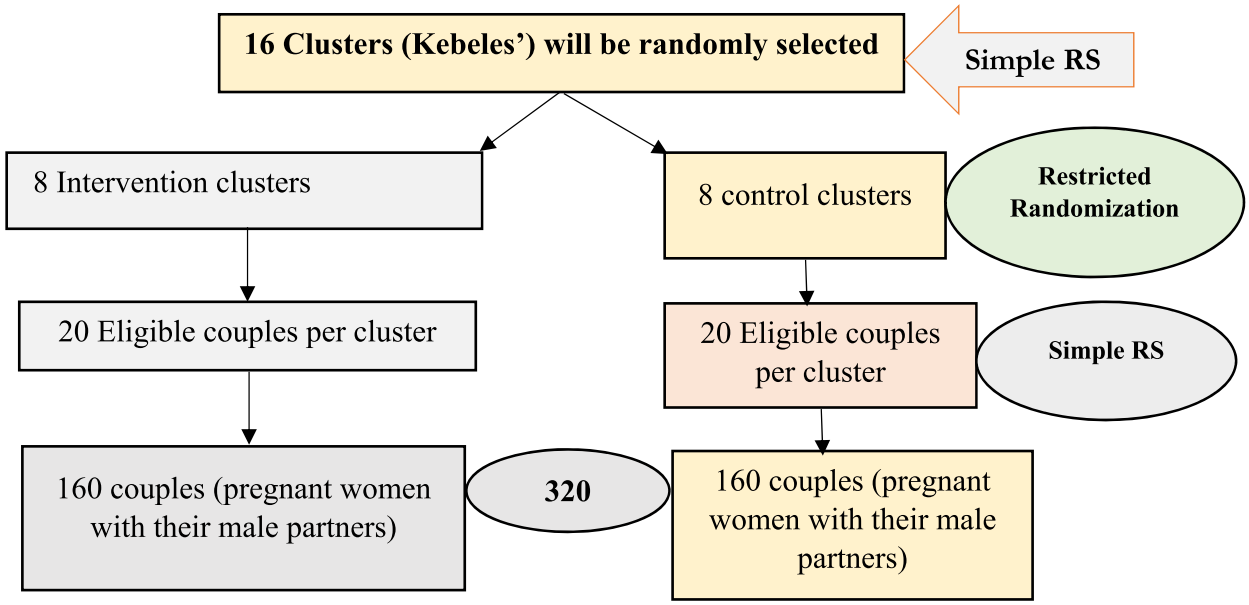

Fig. 1. Schematic presentation of sampling procedure.

gestational age. Women in the beginning of second trimesters (14–16 weeks of gestation) will be listed. This list will be used as a sampling frame. The study participants will be selected from each cluster using simple random sampling technique.

Participants who are voluntary to be involved in the trial along with their spouses (husbands) will be included. Women and their spouses will be requested to confirm their informed consent by putting on their signature to ensure their voluntary participation (S2 Appendix). Once consent is obtained, data will be collected from each participant. The questionnaires contain sociodemographic and obstetrics characteristics, health services usage including MWHs, knowledge and attitudes of MWHs, and male partner participation in MWHs.

2.8. Randomization and blinding

Clusters will be the randomization units, whereas the measurement and analysis units will be the individual participants. The selected 16 non-adjacent clusters are listed alphabetically. Restricted randomization with a 1:1 allocation will be used to assign the clusters to the intervention or control groups. A list of random numbers will be created in Microsoft Excel 2010, and the generated values will be fixed by copying them as "values" next to the alphabetic list of the clusters. The first eight will be chosen as intervention clusters, and the last eight will be chosen as control clusters, in ascending order, based on the produced random numbers. Furthermore, a statistician who is blind to the study groups and is not involved in the research will create the allocation sequence and randomize the clusters. The distribution of clusters to the intervention or control groups will be hidden from the data collectors or outcome assessors.

2.9. Information contamination reduction

At least one cluster will be left between any two clusters that do not share boundaries with each other. This will serve as a buffer zone technique. The participants in the intervention cluster will be informed about the study design and will be requested not to share the received health education messages with others of different clusters until the intervention period is concluded.

3. Brief description of the intervention

The intervention will be provided at three contact points. The first contact will be group health education at baseline whereas the second and third contacts will be home visits.

4. Implementation of the intervention

Group health education will be provided once in the first month (18–19 weeks of gestation), whereas home visits will be performed twice at two-month intervals at 26–27 and 34–35 weeks of gestation. Leaflets will be provided at each of the three contact points.

Group health education: The health education session will be provided in a group for 90–120 min. All participants in the intervention arm within a cluster will be gathered at one common location and will receive health education. Rural health extension workers and cluster leaders will select the place of health education and invite participants. The participants will be invited to receive health education. This will be done in all eight intervention clusters, and as a result, eight health education sessions will be performed at baseline. The health education will emphasize on the purpose and benefits of MWHs and paternal support. Issues such as the importance of antenatal care and the advantages of skilled birth will also be addressed. The services available at MWHs, benefits of staying at MWHs, the right time to visit MWHs, and the importance of paternal support will be discussed. Types of paternal support during pregnancy and MWH stays, such as allowing a spouse to stay at MWH, accompanying her to MWH, providing financial support during MWH stays, providing food and other necessary materials, looking after the home, and caring for the remaining children at home, will be addressed. Health messages in leaflets will focus on paternal support and the purpose and advantages of MWHs. Next, the schedule of home visits will be proposed through discussions with the participants, with an emphasis that both women and their male partners will be contacted at their residence.

Home visit 1: The first home visit will be conducted two months after the health education intervention at 26–27 weeks of gestation. During this visit, participants will receive advice regarding antenatal care, paternal support, and MWHs. Male partners will be advised on how to support their wives and encourage them to use antenatal care, stay at MWHs, and deliver at health facilities. Furthermore, participants will be asked to discuss their perceptions of antenatal care, MWH use, and health facility delivery. Based on their perceptions and actual observed practices, they will be advised. Leaflets with the same health messages as the baseline health education will be provided. At least two visits will be made if participants are absent.

Home visit 2: The second home visit will be conducted two months after the first home visit (at 34–35 weeks of gestation). Paternal support, birth preparedness plans, and intention to use MWH will be assessed during this visit. Leaflets containing messages regarding the possible risks of home delivery and the advantages of using MWHs and institutional delivery will be provided. Any misunderstandings or misperceptions regarding MWHs will be clarified through discussion. Male partners will be advised to continue supporting their spouses. The expected delivery date will be estimated and a possible appointment to arrive at the MWH will be made. To make the woman and her partner remember the appointment, a written invitation letter will be provided. However, the woman will be advised to attend antenatal care, follow the advice of health professionals, and come to a health facility if she experiences any illness. Similar to the first visit, at least two visits will be made if participants are absent. The study findings will be reported using Consolidated Standards of Reporting Trials (CONSORT) for cluster randomized trials criteria [19] (Fig. 2).

4.1. Usual standard of care

The usual health promotion and disease prevention services are delivered to the public in the research project setting as part of primary healthcare. Ethiopian rural health extension program included various health services including infection prevention, family planning, individual and environmental sanitation, and health information and communication [20]. Consequently, village health extension workers encourage modern contraceptive use, antenatal care use, health facility delivery, and other family health matters. These health services are common to all families in the research project setting. The participants in the control group will get these services only. They will not receive other intervention packages such as health education, home visits, or delivery of leaflets. However,

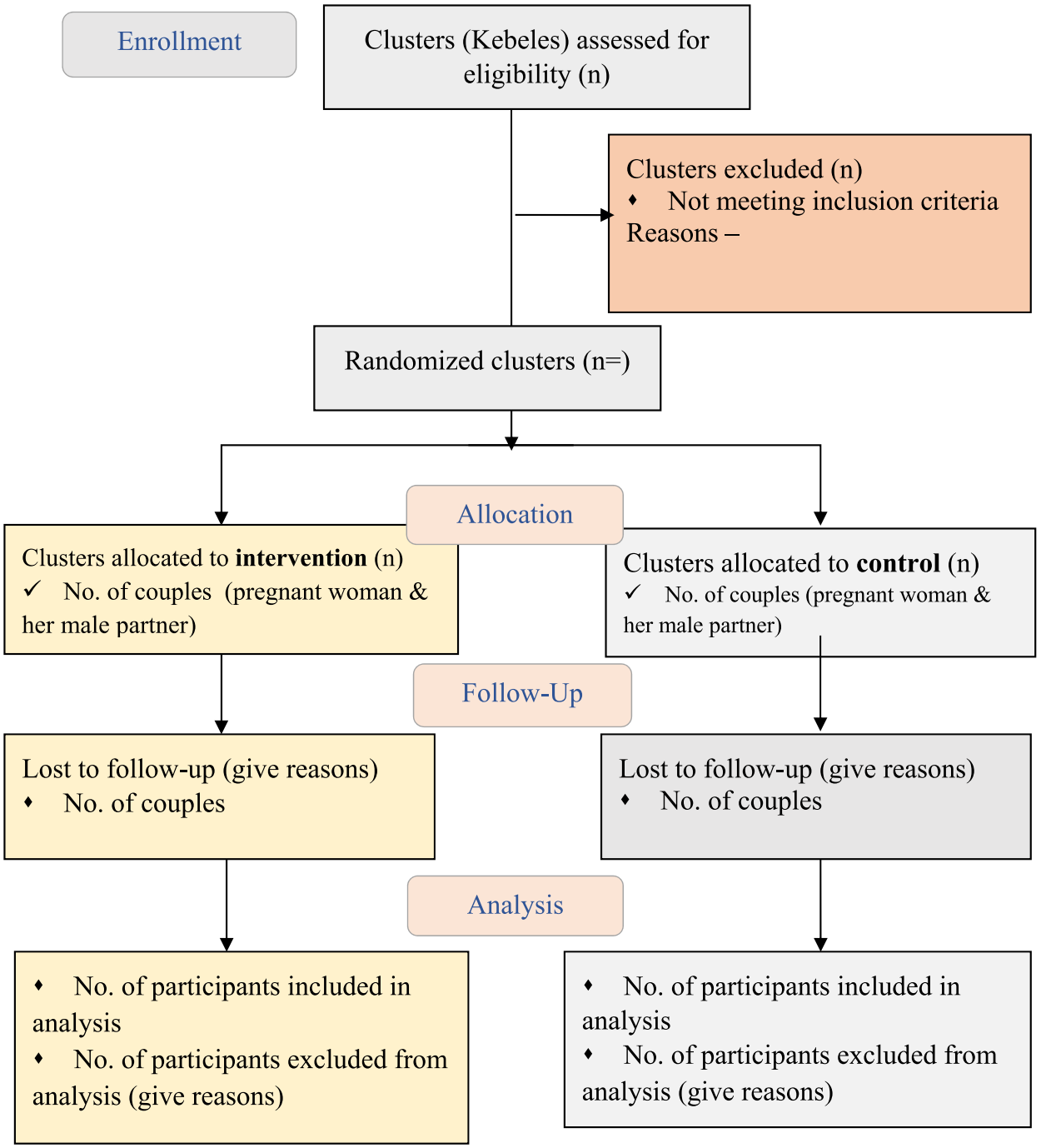

Fig. 2. CONSORT flow diagram.

the control group will be given the intervention at the end of the project period.

4.2. Services available at MWHs

Women who stay at MWHs receive the services based on the national guideline [21]. Sleeping rooms are delivered upon arrival. Antenatal check-ups and follow-ups by health workers are the basic existing health services. In this research project, the MWH staff will be informed to welcome the male partners of pregnant women and encourage them to support their spouses throughout their stay at MWHs. In addition to the registration book at the MWH, a distinct recordkeeping format will be used.

4.3. Compliance parameter

The attendance sheet of participants recorded at the three contact points will be used to determine their compliance with the intervention (Table 1).

4.4. Primary outcome

The percentage of MWH use will be assessed. The use of MWHs can be traced through home-to-home surveys and record reviews at MWHs. The percentage of MWH use will be computed for each study group at the beginning and end of the study period. The effect of the intervention will be assessed as a difference-in-differences in the percentage of MWH use between the study groups.

4.5. Secondary outcomes

At the start and end of the study term, assessments of knowledge and attitude will be performed. Comparisons will be made between the trial arms on the knowledge and attitudes gained from the intervention. Yes/No questions will be used to assess knowledge. The number one (1) will stand for "Yes," and the number zero (0) will stand for "No." Then, a respondent's total average that is higher than the median will be regarded as having good knowledge, and vice versa. A 5-point Likert scale will be used to measure attitudes (very disagree, disagree, neutral, agree, very agree). Any average score that is higher than the median will be inferred as favorable attitude.

4.6. Reliability of measures

The data collection tool will be adapted from different studies and structured to fit the study situation, which adds to the reliability of the assessments. The reliability of the evaluation items will be assessed using Cronbach's alpha and applicable corrections will be made based on the test results. The Cronbach's alpha cut-off value will be ≥ 0.70. Furthermore, data collectors will be trained on the standards and techniques of data collection.

4.7. Activity schedule

Participants enrollment, intervention and assessment schedule is summarized as follows (Table 2).

4.8. Data collection methods

Home-to-home surveys will be performed to gather data using pretested structured questionnaires. Following the completion of the participant recruitment process, baseline data will be gathered. At the conclusion of the intervention, the endline data will be gathered. Assessments will be made on study variables such as sociodemographic characters, knowledge, attitude, and utilization of health services, containing MWH usage.

4.9. Confidentiality

The confidentiality of study participants will be considered. The completed data checklist will be removed from the questionnaires after data collection, and codes will be given to each questionnaire. The removed checklists will be kept in a safe place until it will be discarded. The codes assigned to each participant will be used.

Table 1
Summary of the trial protocol.

Packages of intervention	Dosage	Frequency	Duration	Compliance parameter
Group health education (+leaflets)	90–120 min	Once	1 month	#participants contacted at group health education
Home visits (+leaflets)	30–45 min	Twice	2 months	#participants contacted at home visits

Table 2
Schedule of enrolment, interventions and assessments.

		STUDY PERIOD							
		Enrolment & Allocation	Post-allocation (Intervention Phase)						Close out
Time point		$t_{(-1)}$	t_1	t_2	t_3	t_4	t_5	t_6	$t_{(+1)}$
Enrolment	Eligibility screening								
	Informed consent								
	Allocation								
Interventions	Health Education (+Leaflets)								
	Home Visits (+Leaflets)								
Assessments	Baseline data collection								
	Endline data collection								

4.10. Data management

Clusters and participant will be coded. Data will be entered into Epi info version 7.2.5., edited, and transported to SPSS or STATA software for statistical analysis.

4.11. Statistical analysis

The data analysis will be performed using SPSS or STATA software. The participants will be assigned to clusters based on where they live at the start of the trial. The participants knowledge of MWH, attitude towards MWH, and uptake of MWH will be computed at baseline and endline for both intervention and control groups. The outcome measures between the intervention and control arms will be compared using the Pearson's chi-square test of independence. The difference-in-difference (diff-in-diff) estimator will be used to estimate the net effect of the intervention, as the baseline outcome will not determine the cluster allocation [22]. Moreover, generalized linear model regressions will be performed to determine the odds of outcomes between the intervention and control groups. The data will be analyzed using an intention-to-treat approach. The statistical significance will be declared at $p < 0.05$ with 95 % confidence interval.

4.12. Data monitoring

The researchers will form a group of supervisors to monitor and audit the data-gathering process at baseline and endline evaluations.

4.13. Plan of dissemination

The trial results will be shared with concerned stakeholders in the health sector and other governmental and non-governmental bodies. The findings will also be disseminated to scientific scholars through publications and conference presentations.

5. Discussion

In Ethiopia, the use of MWHs is low and its rates vary across regions in the country. Although the WHO recommends further research to investigate the possible strategies that could be effective in increasing the usage of existing MWHs, interventional research aimed at enhancing MWH use is scarce. Hence this CRT aims to examine the effect of delivering health education to couples on MWH use among mothers in rural Ethiopia. The findings also may help policymakers and medical practitioners to design viable strategies to enhance women's access to MWHs and other maternal health services in rural Ethiopia.

5.1. Protocol amendment

Any alterations to this study protocol, such as adjustments to the goals, population, design, sample size, or methods, will be reported to Jimma University's Institutional Review Board (IRB) and approved before implementation.

Ethics approval

For this study, we received an ethical approval letter (with ref. no. JUIRB-33/22 on February 09, 2022) from Jimma University's IRB. A permission in writing will be sought from the Hadiya Zone Health Department in Southern Ethiopia before any data-gathering begins. All participants will be made aware about the aims of the study and their written consent will be obtained.

Consent for publication

Not applicable.

Funding

Jimma University will cover the data collection costs of this study; however, it will not fund the other tasks including data analysis and publications. Jimma University has no role in the publication of this study.

Availability of data and materials

No data available. All additional information is annexed.

CRediT authorship contribution statement

Teklemariam Ergat Yarinbab: Writing – review & editing, Writing – original draft, Software, Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Hailay Abrha Gesesew:** Writing – review & editing, Supervision, Methodology, Investigation, Conceptualization. **Tefera Belachew:** Writing – review & editing, Supervision, Methodology, Investigation, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.heliyon.2024.e31791.

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